

PATENT
674583-2001**REMARKS**

Reconsideration and withdrawal of the Restriction Requirement is respectfully requested in view of the remarks herein.

The Office Action required restriction from among:

- Group I: Claims 1-8, drawn to a composition comprising FIX and FVIII together for simultaneous use in the treatment of haemophilia A or B; and a method of manufacture of a composition using FIX and FVIII together, classified in class 50, subclass 383, and class 50, subclass 384, respectively; and claims 13-15, drawn to a method for potentiating FVIII, where FVIII and FIX are used together in a composition, classified in class 50, subclass 384;
- Group II: Claims 1-3, drawn to a composition comprising FIX and a separate composition comprising FVIII for separate use in the treatment of haemophilia A or B, classified in class 50, subclass 383, and class 50, subclass 384, respectively;
- Group III: Claims 9-12, drawn to a method of treatment of haemophilia A or B using a composition comprising FIX and FVIII together, classified in class 50, subclass 383, and class 50, subclass 384, respectively; and,
- Group IV: Claims 16 and 17, drawn to a method for reducing the immunogenicity of FVIII by administering FIX and FVIII together as one composition, classified in class 50, subclass 384.

Applicants elect, with traverse, the claims of Group I, namely claims 1-8.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “ [i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

Thus, for a restriction requirement to be proper, it must satisfy both of the above elements. Accordingly, the present restriction requirement is improper and must be withdrawn because the Office Action only alleges that the inventions are distinct, which allegation is traversed. The Office Action provides no showing that search and examination of the claims of

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Groups I-IV would be an undue and serious burden. Therefore, the restriction requirement is improper because it does not satisfy both requirements for restriction.

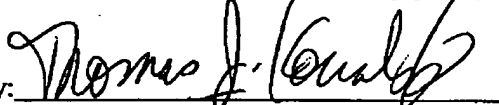
It is also respectfully submitted that the present claims represent a web of knowledge and continuity of effort that merits examination in a single application. Therefore, reconsideration and withdrawal of the Restriction Requirement are warranted. Furthermore, the Office Action specifically states that product claims are elected, upon allowance of a product claim, the Restriction Requirement between the product and process claims would be withdrawn, and the claims would be rejoined. Applicants respectfully request that at the very least, this rejoinder of product and process claims, namely the claims of Groups I and III. Rejoinder of the claims now, instead of after allowance of a product claim, will prevent delays and other prejudices to the Applicant that would occur if the rejoinder occurred after allowance of the product claims.

In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested.

Respectfully submitted,
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